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Kancera signs license agreement and obtains global commercial rights to the results from the FRACTAL study

In connection with the interim report for the fourth quarter 2023, Kancera AB (publ) today provides a general operational update and reports that the company has signed a license agreement with the University of Newcastle. Through this agreement, Kancera is granted the exclusive global commercial rights to the results from the FRACTAL study, including full ownership of a new clinical use patent.

Kancera AB (Kancera) is developing two fractalkine blocking drug candidates, KAND567 and KAND145, that are currently being studied in three ongoing clinical trials:

The FRACTAL study

The FRACTAL study is an exploratory clinical phase IIa study of KAND567 in high-risk ST-elevation myocardial infarction (STEMI) patients, undergoing percutaneous coronary intervention (PCI). The study has been conducted in collaboration with the University of Newcastle and the Newcastle upon Tyne Hospitals NHS Foundation Trust, sponsor of the study. In December 2023, Kancera reported positive top line results from the study; both the primary and secondary objectives were met by demonstrating a favorable safety profile and giving signals of cardio-protective effects.

Since the top line results were reported, Kancera has received the complete study database from the University of Newcastle, validated the results and conducted detailed statistical analyses, including sub-group analyses. The statistical analyses support that KAND567 has the potential to:

- Reduce intramyocardial hemorrhage
- Reduce the size of the infarction in patients without intramyocardial hemorrhage
- Reduce left ventricular thrombosis

The first two effects are demonstrated as a statistical trend. The third effect is shown with statistical significance, meaning that Kancera has demonstrated the first evidence of KAND567's clinical effect, i.e. "proof-of-concept". Taken together, Kancera views these effects as being of high clinical relevance, since they are markers for well-established primary efficacy endpoints in pivotal studies, such as heart failure and stroke.

Kancera today reports that it has entered into a license agreement with the University of Newcastle, through which Kancera is granted the exclusive global commercial rights to the results from the FRACTAL study. In consideration of the granted rights, Kancera will pay a one-off fee to the University of Newcastle. Kancera further announces that a patent application has been filed, which covers the use of KAND567 and KAND145 for treatment of myocardial infarction. Through the executed license agreement, Kancera assumes full ownership of this patent application. The term of this clinical use patent, if granted, will run to 2044.

The KANDOVA study

The KANDOVA study is a combined phase Ib/IIa study of KAND567 in combination with carboplatin in ovarian cancer patients. The objective of the phase Ib part of the study is to define the maximum tolerated dose of KAND567, which will then be used in the phase IIa part to evaluate efficacy.

Patient recruitment is now ongoing at five university hospitals in Sweden, Norway and Denmark. Aiming to increase the number of eligible patients, Kancera has submitted an amendment to the study protocol. This amendment has now been approved by all regulatory authorities and ethical committees in Sweden, Norway and Denmark. As expected, the implementation of the amended protocol has resulted

in an increased number of patients meeting the study's inclusion criteria. 3 patients have now been recruited and there is a clear indication that additional patients will be added. Depending on the dose that is recommended for phase IIa, Kancera expects that 6-12 patients will be required to finalize phase Ib. Kancera's objective to finalize phase Ib by the end of Q2 2024 remains unchanged.

Phase I study of KAND145
The study is a first-in-human study, in which peroral administration of KAND145 in healthy subjects is evaluated. The objective is to evaluate safety, tolerability, pharmacokinetics, food effect and drug interaction. The study consists of two parts: single ascending dosing in part one and multiple ascending dosing in part two.

Kancera today reports that the first part of the study has been completed and that the safety review committee has made the decision to start part two. The first cohort with multiple ascending dosing is now ongoing. Based on the results from part one, Kancera today reports the following results:

- KAND145 is effectively dephosphorylated in human to the pharmacologically active moiety KAND567, as expected and in line with previous preclinical studies
- Following dephosphorylation, the pharmacokinetic profile is equal to dosing with KAND567
- When administered as single dose, KAND145 is safe and tolerable at concentrations expected to be therapeutically effective in treatment of inflammatory conditions

Through these results, Kancera has reached an important milestone with a second candidate drug that has demonstrated adequate pharmaceutical properties in human, and confirmation in human that KAND145's mechanism of action is identical to KAND567's. Accordingly, these results validate Kancera's strategy, to evaluate the concept of fractalkine blockers using KAND567 as a lead, in parallel with the first clinical studies of the second generation KAND145.

As a very simple aqueous concentrate formulation for dilution for oral use is being used in the ongoing phase I study, Kancera intends to conduct formulation development of KAND145 with the objective to develop an oral formulation that is optimized for tolerability at the highest anticipated dose levels required for cancer indications. This formulation development will be conducted in parallel with the ongoing clinical development in cancer using KAND567.

Non-proprietary names
Kancera has filed applications to WHO to obtain non-proprietary names (INN) for KAND567 and KAND145. The decision on granting of the requested non-proprietary names will be made by WHO's INN Committee and is expected to be conveyed to Kancera in May 2024.

About Kancera AB (publ)
Kancera is developing a new class of small molecule drugs targeting the fractalkine axis. Kancera's main focus is to develop its candidate drugs for treatment of severe inflammatory diseases and cancer that currently lack effective treatments. The stock is traded on the Nasdaq First North Premier Growth Market. FNCA Sweden AB is the company's Certified Adviser.

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